

Expanding Scope of Drugs that can be subject of patent term extension

The Israeli Patents Law was amended in 1998, when provisions were introduced for patent term extension in order to permit ethical drug manufacturers to extend the life of their patent. Experimental use provisions were also introduced to permit generic drug manufacturers to develop a generic drug substitute for a patented drug during the life of the patent.

The enactment of this Amendment was met with some concerns and some of the newly introduced provisions came under considerable criticism in many circles.

Among the concerns voiced was whether the effects of the Law would limit drug-related patent rights in Israel. So far, these concerns have not materialized and the recent development reported below seems to point, at least insofar as the position of the Patent Office is concerned, that matters have gone in the opposite direction, towards the strengthening of patent rights in favor of patent owners.

The Amendment of the Law which was enacted in haste includes a number of ambiguities, some of which will no doubt be tested in the future. One such ambiguity that came to test very recently, concerns the definition of who is entitled to file an application for patent term extension. The section of the Law that was at issue is Section 64C(a) which reads as follows:

"The holder of a basic patent and the holder of an exclusive license may apply for an extension order."

It may be noted that, under this Section, those entitled to file an application for an "extension order" (the term used in the Law for patent term extension) are the holders of a basic patent and the holders of an exclusive license.

The Law stipulates that an application for patent term extension must be filed within 60 days from receipt of Marketing Approval from the Ministry of Health (MOH) which is the authority in Israel that issues marketing approvals. And here lies the problem.

In some fields and under certain circumstances (e.g. in certain biotechnology cases), there are great delays in prosecution of patent applications and it may happen that the drug is approved for marketing even before the patent has issued. The situation can be further aggravated if an opposition is filed, as oppositions in Israel are pre-grant proceedings. Consequently, given the fact that patent term extension can only be applied for by the patentee or the exclusive licensee and that the application must be filed within 60 days, in the event of a patent that has not yet issued, the right to patent term extension will be lost.

This was the initial position taken by the Israeli Patent Office in three different applications for patent term extension filed on behalf of three different large foreign corporations, which were handled by our firm. The Patent Office's initial position was, that, given the provisions of Section 64C(a), the application is not valid and should be refused in limine.

A petition was filed by our firm on behalf of these three applicants basically pointing out that the position of the Patent Office did great injustice to such ethical drug developers. It was argued that on top of loss of effective patent rights as a result of the prosecution delays that occurred through no fault of the applicants, under

such construction of the Law, the applicants also lose additional rights in view of their inability to file an application for patent term extension. Arguments were brought forward to show that the manner of interpretation of the Law goes against its spirit and against the intention of the legislator in enacting the Amendment. These arguments were fortified by a thorough review of comparative law. In the arguments presented to the Patent Office a legally sound solution was proposed, by way of granting an extension of time to the ethical drug developer for filing an application for patent term extension in all such cases until after the patent has issued. This is similar to the legal situation in Europe, for example, where the term to file an application for patent term extension expires six months after drug approval or six months after date of grant of the patent whichever the later date.

We are pleased to report that, in a decision issued by the Deputy Registrar on January 2, 2002 our position in the petition was accepted. The registrar has discretion under Section 164 of the Law to extend most prescribed terms (with a few exceptions). In the Decision it was ruled that in cases such as this, where the drug received marketing approval before that patent issues, the Registrar will act in accordance with his/her discretion and the term to file an application for an extension order will be extended until 60 days after the patent issued, if indeed issued.

In arriving at this decision it clearly follows that the policy of the Israeli Patent Office is and remains pro-patent. This decision further strengthens the patent rights afforded by the Israeli Patents Law.

Recommendation:

We recommend that in all cases where drug approval is obtained prior to grant of the patent, an application for extension of time for filing the application for extension of term will be submitted, within 60 days of the drug approval, to the Patent Office. We also strongly recommend that, during the period in which the patent application is still pending, you provide us with all necessary documents to enable us to prepare an application for patent term extension. In this way, we can file the application immediately, once the patent issues.